JUL 1 4 2000

SUMMARY OF SAFETY AND EFFECTIVENESS

Sponsor:

Biomet, Inc.
56 East Bell Drive
Warsaw, Indiana 46580

K001271

Device:

Samarco Spider Plates

Classification Name:

Single/multiple component metallic bone fixation appliances and accessories

Intended Use:

These plates are intended for use for 1) fresh fractures; 2) osteotomies; 3) revision procedures where other treatments or devices have failed; and 4) arthrodesis.

Device Description:

The Samarco Spider Plate is a single component metallic bone fixation appliance that offers the user a great deal of variability in the configuration of the plate. There are eight "legs" that can be bent and cut to the necessary configuration. There are two sizes of plates available. The larger size plate is available in four different configurations. The plates are fixed using standard bone screws.

Potential Risks:

1. Nonunion or delayed union which may lead to breakage of the implant.
2. Bending or fracture of the implant.
3. Loosening or migration of the implant.
4. Metal sensitivity, or allergic reaction to a foreign body.
5. Limb shortening due to compression of the fracture or bone resorption.
6. Decrease in bone density due to stress shielding.
7. Pain, discomfort, or abnormal sensation due to the presence of the device.
8. Nerve damage due to surgical trauma.
9. Necrosis of bone.
10. Postoperative bone fracture and pain
11. Inadequate healing.

Substantial Equivalence:

In function and overall design the Prosthesis is equivalent to other commercially available trauma plating systems currently on the market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 4 2000

Ms. Mary L. Verstynen
Manager of Clinical Affairs
Biomet, Incorporated
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K001271
Trade Name: Samarco Spider Plates
Regulatory Class: II
Product Code: KTW
Dated: April 19, 2000
Received: April 20, 2000

Dear Ms. Verstynen:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) Number (if known) : K001271

Device Name: Samarco Spider Plates

Indications For Use: 1) Fresh fractures; 2) Osteotomy; 3) Revision procedures where other treatments or devices have failed; 4) Arthrodesis.

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K001271

Prescription Use X
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)